Scope of ASTM E55

"I will tell you that I think that E55 is too narrow in scope. Although PAT is an important factor in moving FDA forward, it is only a subpart of the overall initiative at the agency I would like to see the scope of E55 apply to pharmaceutical manufacturing in general"

Helen Winkle, OPS, FDA

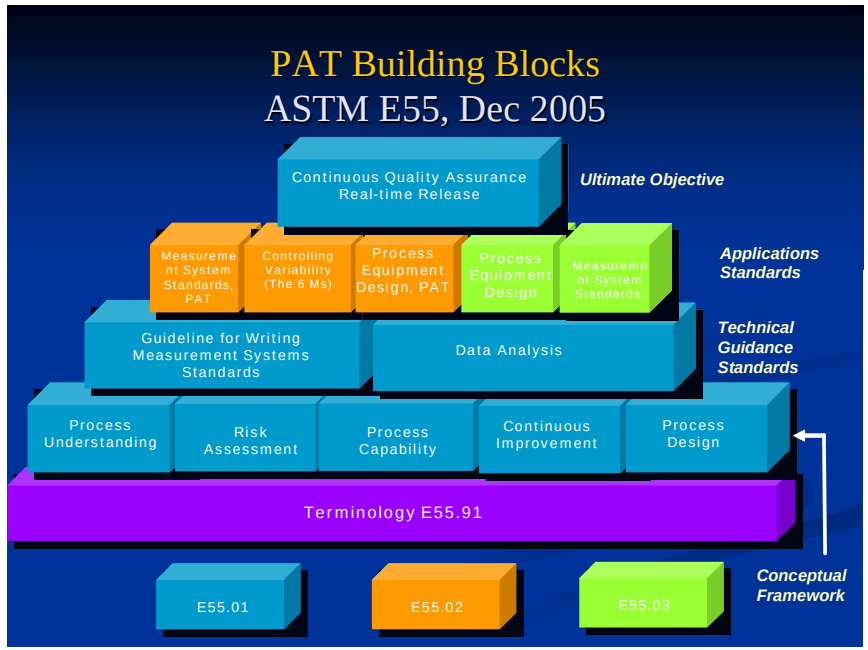
May 2006

Why Consensus Standards?

Regulatory → The WHAT

- "Ensure Purity, Efficacy, Safety, Potency"
- "Validate"
- "Qualify"
- "Traceability"
- "Process Understanding"

Consensus Standards → The HOW



Consensus is developed by representatives of all sectors that have an interest in the use of the standard

"Standards Code of Practice"

TBT Agreement, Section 3
Annex 4 Report of the 3rd Triennial Review of TBT Agreement

- **Open** – all interested parties are invited to participate - transparent
- **Balanced** – no sector (producer, user or government) can dominate
- **Due Process** – all positions are considered – appeal process exists
- **Relevant and Coherent** – standards provide value and avoid duplication

Why is FDA Involved?

- Standards
  - Address elements of the FDA Performance Plan
  - Optimize the utilization of FDA resources
  - Accomplish international trade Commitments
  - Enables cooperation between governments
  - Encourages partnering with manufacturers
  - Enables improvements in industrial productivity by basing requirements on accepted standards
  - National Technology Transfer Act (PL104-113) & OMB Circular A119

How does FDA Use non-Government Standards

- Participation in development does not connote adoption
  - Does the standard address our science or regulatory concerns/issues
- Uses
  - Cite by FDA in Regulation and Guidance
  - Cite by sponsor as part of documentation
  - As forum to discuss science with industry

D. Marlowe, FDA – ASTM Toronto 2006

FDA Support for ASTM

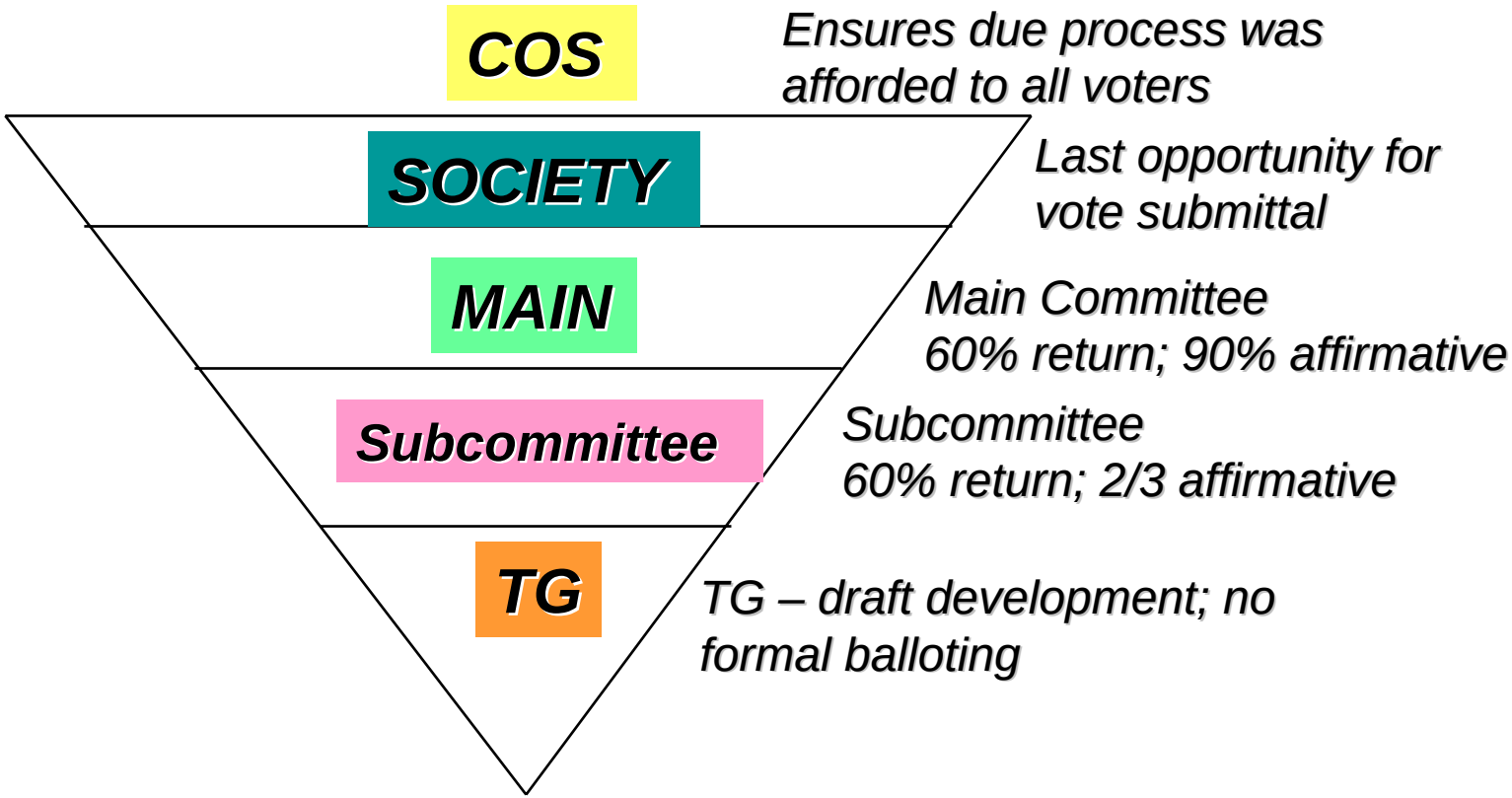
- "…FDA supports the development of voluntary consensus standards. There are various activities in which the Agency can participate with regard to standards development that can be extremely valuable to us now and in the future. This includes:
  - • utilizing standards in place of guidances,
  - • promoting standards development for certain functions, etc., to help support regulation,
  - • participating on standards committees, and
  - • implementing standards to help in understanding.
- The current activities of E55 are just the start."

H. Winkle, FDA – ASTM Toronto 2006 (from Transcript)

Types of Standards in ASTM – The HOW

- **Standard guide**, *n*—a compendium of information or series of options that does not recommend a specific course of action.
  - A guide increases the awareness of information and approaches in a given subject area.
- **Standard practice**, *n*—a definitive set of instructions for performing one or more specific operations that does not produce a test result.
  - Examples of practices include, but are not limited to: application, assessment, cleaning, collection, decontamination, inspection, installation, preparation, sampling, screening, and training.
- **Standard specification**, *n*—an explicit set of requirements to be satisfied by a material, product, system, or service.
  - Examples of specifications include, but are not limited to, requirements for; physical, mechanical, or chemical properties, and safety, quality, or performance criteria. A specification identifies the test methods for determining whether each of the requirements is satisfied.
- **Standard terminology**, *n*—a document comprising definitions of terms; explanations of symbols, abbreviations, or acronyms.
- **Standard test method**, *n*—a definitive procedure that produces a test result.
  - Examples of test methods include, but are not limited to: identification, measurement, and evaluation of one or more qualities, characteristics, or properties. A precision and bias statement shall be reported at the end of a test method. (Refer to Section A21 on Precision and Bias.)

ASTM's Balloting Process



P. Picariello, ASTM – ASTM Toronto 2006

Voting Rights - Voting vs. Non-Voting

- **1 official vote per interest (company)***
- **All are welcome to participate in technical discussions**
- **All members receive a ballot and are eligible to vote on technical issues**
- **All negatives must be considered**

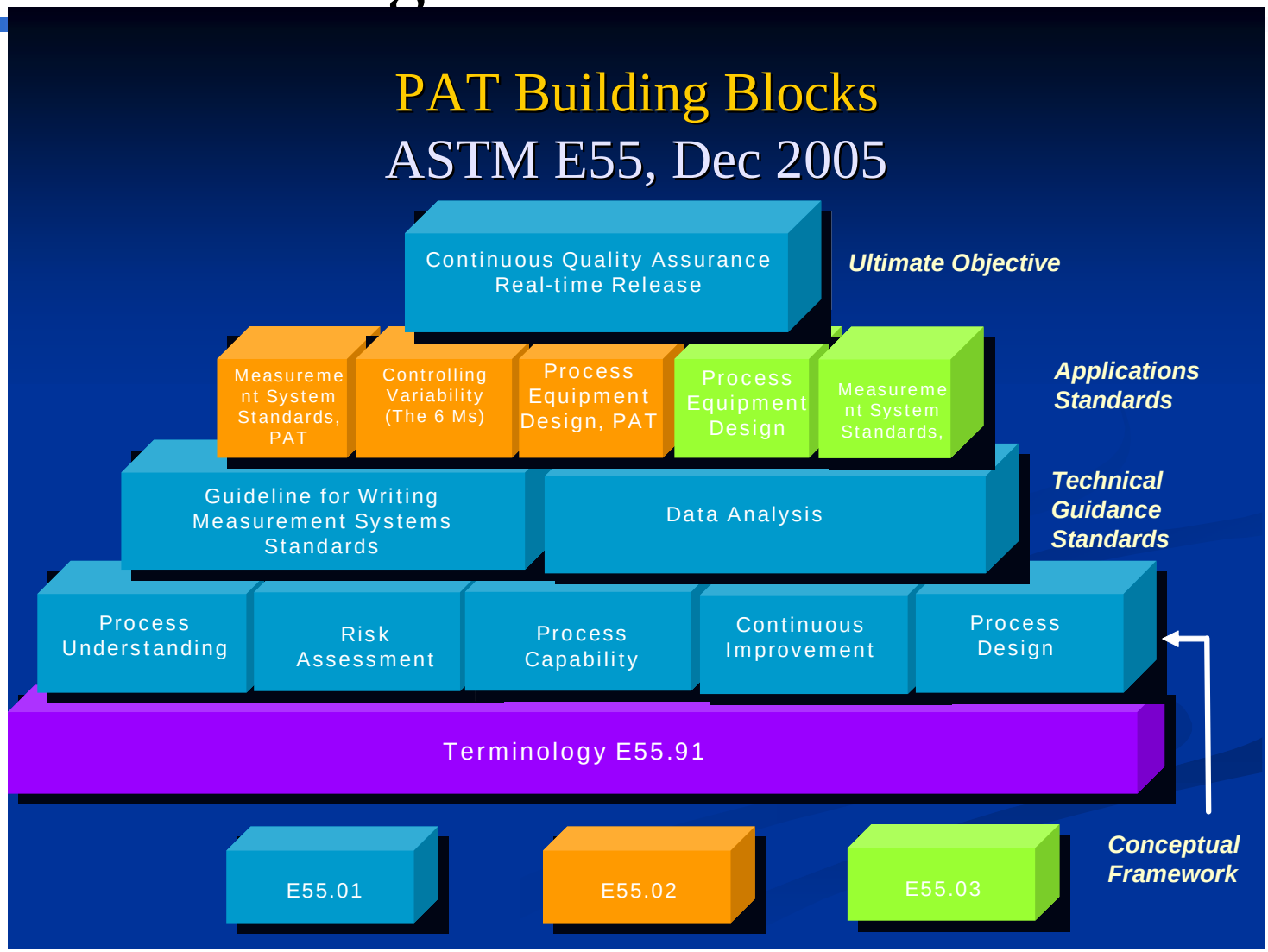
***official vote will be given unless company already represented or receipt of vote would jeopardize balance.**

ASTM E55 Title and Scope*

- **Title**:
  - *Committee E55 on Preparation for, and Application of, Process Analytical Technology in Development and Manufacture of Pharmaceuticals*
- **Scope**:
  - *The scope of the Committee shall be development of standardized nomenclature and definitions of terms, recommended practices, guides, test methods, specifications, and performance standards for preparation for, and application of, process analytical technology in the development and manufacture of pharmaceuticals. The Committee will encourage research in this field and sponsor symposia, workshops and publications to facilitate the development of such standards. The Committee will promote liaison with other ASTM Committees and other organizations with mutual interests.*

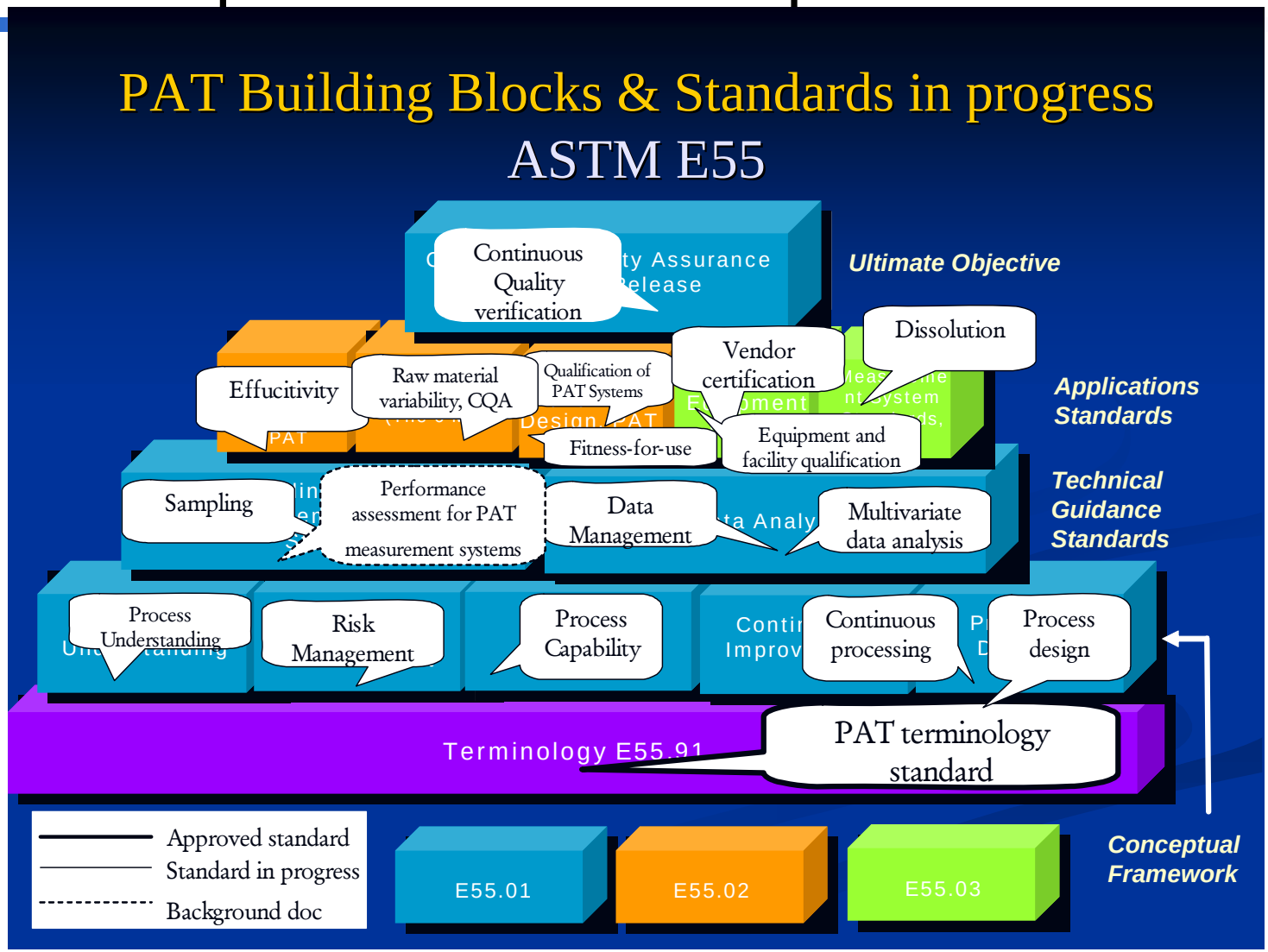
*Recently approved through ballot

ASTM Building Blocks – 2006+



ASTM E55 Executive

The Complete E55 Workspace



ASTM E55 Executive

Detailed Work Items

Subcommittee E55.01

- WK5930 Standard Practice for Risk Management as it Impacts the Design and Development of Processes for Pharmaceutical
- WK5935 Standard Practice for Process Understanding Related to Pharmaceutical Manufacture and Control
- WK9192 Standard Guide for the Application of Continuous Processing Technology to the Manufacture of Pharmaceutical Products
- WK9645 Standard Guide for Application of Process Capability

Subcommittee E55.02

- WK4185 Test Method for the Measurement of Thermal Effusivity of Raw and Process Materials
- WK4694 Guide to Assure Fitness-for-Use of a Measurement System to Determine or Control Process or Product Quality Attributes
- WK5015 Pharmaceutical Process Design
- WK5931 Standard Practice for PAT Data Management
- WK9182 Standard Practice for Qualification of PAT Systems
- WK9191 Standard Practices for Multivariate Analysis Related to Process Analytical Technology

Subcommittee E55.03

- WK9864 Standard Guide to a Science and Risk-Based Approach to Qualification of Biopharmaceutical and Pharmaceutical Manufacturing Systems
- WK9935 Standard Guide for the Application of Continuous Quality Verification to Pharmaceutical Manufacturing
- WK9936 Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus

Frequently Asked Questions

- "How is this different from ICH?"
  - **ICH Purpose** - "The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines."
  - ASTM standards help establish the HOW
- "Won't this clash with regulatory standards or pharmacopeias?"
  - Regulatory bodies are trying to focus on the WHAT.
  - In the US the NTTAA and OMB A119 established policy to encourage the use of consensus standards where practical.
  - Pharmacopoeia standards focus on specifications for materials and products
- "Do I have to follow a standard just because it exists?"
  - ASTM standards are voluntary consensus standards. Unless specifically referenced by regulatory authority or demanded by a customer a standard is considered voluntary.
- "Will the regulatory authorities enforce ASTM standards?"
  - Regulatory authorities can cite consensus standards in their guidance or law.
- "Will the regulatory authorities ignore ASTM standards?"
  - In the US, the authorities can only ignore them when they are inconsistent with the law or otherwise impractical to follow.
- "Can a majority of interests force through standards to gain an economic or political advantage on a minority interest?"
  - A 60% affirmative is required at the subcommittee level
  - A 90% affirmative is required at the committee level
  - All negatives evaluated for persuasive content

Conclusion

- The ASTM process benefits all parties
  - Consensus based
  - Engages experts and key stakeholders
  - Balanced and fair
- The quality of the standards depend upon quality participation
- Join Today
  - www.astm.org